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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

DR. JAMES M. SWANSON, an individual,

Plaintiff and Counterdefendant,

vs.

ALZA CORPORATION, a corporation,

Defendant and Counterclaimant.

Case No. 4:12-cv-04579-PJH-KAW

PLAINTIFF DR. JAMES M. SWANSON'S OPPOSITION TO ALZA COPRORATION'S MOTION FOR SUMMARY JUDGMENT

Date: November 19, 2014
Time: 9:00 a.m.
Courtroom: 3
The Honorable Phyllis J. Hamilton

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I. INTRODUCTION

In its Motion for Summary Judgment ("Motion"), Defendant ALZA Corporation ("ALZA") contends that the only correct inventors of the Patents-In-Suit are individuals who were employed at ALZA in 1994. ALZA makes this claim despite the fact that no ALZA scientist at that time had any experience with treating individuals for ADD or ADHD or any experience with the effects of methylphenidate on individuals suffering from these conditions.

Instead, ALZA contends that Plaintiff Dr. James Swanson ("Dr. Swanson"), an acknowledged expert in the field of treatment of ADD and ADHD, who designed and researched clinical studies of children suffering from these conditions with respect to the efficacy of methylphenidate and the levels of dosage and duration of that drug on the behavior of children, made no contribution to the inventions of the Patents-In-Suit. The claims of those patents cover methods for treating conditions involving the administration of a pharmaceutically acceptable composition of methylphenidate in a manner that achieves a profile in which the plasma concentration of methylphenidate generally rises over a specified daily time period. Despite those admitted facts, ALZA argues that Dr. Swanson provided no inventive contributions whatsoever to the claims of the Patents-In-Suit. Simple logic compels the conclusion that ALZA's contention lacks merit. The facts and law discussed in this brief are more than sufficient to defeat ALZA's Motion which should be denied in all respects.

A. Dr. Swanson's Inventorship Contentions

In its Motion, ALZA mistakenly argues that "Plaintiff consistently alleges he conceived of ***only one thing***: thrice-daily (TID) administration of equal doses of immediate-release methylphenidate (IR-MPH). . ." (Dkt. 170 at 1) (emphasis added). In support of this argument, ALZA cherry picked various quotations from Dr. Swanson's Declaration In Support Of His Inventorship Contentions ("Swanson Inventorship Decl.") (which is attached as Exhibit A to Declaration of Robert J. Yorio In Support of Dr. Swanson's Opposition to ALZA's Motion for Summary Judgment ("Yorio Decl.")[1], and concealed relevant testimony that shows material issues

[1] Dr. Swanson's Declaration In Support of His Inventorship Contentions is attached as Exhibit A to the Declaration of Robert J. Yorio. Unless otherwise indicated, references to "Ex." refer to exhibits to the Yorio Decl.

of fact. Overall, Dr. Swanson demonstrates where his Inventorship Contentions allege conception of the claims of the '129 Patent, as construed by the Court.

"wherein the method comprises administering a pharmaceutically acceptable composition comprising methylphenidate and a pharmaceutically acceptable carrier to said patient"

As construed by the Court, this claim limitation means "administering a pharmaceutically acceptable composition comprising methylphenidate once-daily." (Dkt. 157 at 29). This inventive step was conceived by Dr. Swanson and is specifically addressed in his Declaration In Support of his Inventorship Contentions, which provides as follows:

- I also recommended the ***need for a once a day pill*** that was being considered by the ALZA group. [FN14] As evidenced by the December 6, 1993 agenda, ALZA ***still had not decided*** upon the methylphenidate delivery system to employ (i.e. TTS® skin patch or OROS® pill). I recommended a once a day pill delivery system in order for children to avoid the potential embarrassment of having to wear a patch at school. (Ex. A at 12) (emphasis added).

"in a manner that achieves a substantially ascending methylphenidate plasma drug concentration over a time period of about 8 hours following said administration."

Under the Court's Claim Construction Order, this means "a profile in which the plasma concentration of methylphenidate generally rises over approximately [x] hours." (Dkt. 157 at 29). Dr. Swanson conceived this novel discovery as well and discussed it with ALZA at the December 6, 1993 consultant meeting. In arguing that Dr. Swanson did not bring this idea with him to the consultant meeting, ALZA deceptively crops a quotation from Dr. Swanson's Inventorship Declaration:

- [B]efore ever meeting with anyone from ALZA, I knew the optimal pattern for treatment of ADHD was three times a day dosing and had stated this opinion in several publications, why this would be so. I presented my findings to the ALZA group **. . .**" (Dkt. 170 at 6) (ellipses emphasized)

- However, the sentence that ALZA cut off continued to go on to say ". . . to the ALZA group ***about the plasma concentrations of methylphenidate and its major metabolite (ritalinic acid) of this regime that produced substantially ascending methylphenidate plasma concentrations across the day.***" (Ex. A at 12) (emphasis added).

Taken *in context*, the full quote provides Dr. Swanson's relevant testimony in his Inventorship Declaration demonstrating a triable issue of material fact.

Dr. Swanson also demonstrates where his Inventorship Contentions allege co-inventorship of Claims 1 and 7 of the '798 Patent. First, as discussed above, Dr. Swanson advocated and contributed to the conception of an oral pill form since ALZA had not settled on a pill or skin patch form. (Ex. A at 12). Second, Dr. Swanson at least contributed to the immediate release portion of the pill. From his prior work he advocated an initial bolus of MPH which was initially rejected by ALZA. (*Id*. at 15, 17). Dr. Swanson's testimony, as well as corroborating evidence discussed below, establishes triable issues of material fact which amount to clear and convincing evidence of inventorship.

B. Summary of Dr. Swanson's Work Prior to Meeting with ALZA on December 6, 1993

Beginning in 1975, Dr. Swanson worked with methylphenidate ("MPH"), particularly with its use in the clinical treatment of children and adolescents suffering from ADD and ADHD. Sometime prior to 1993, and because of his extensive experience with ADD/ADHD, Dr. Swanson was selected to serve as a member of the Psychopharmacology Committee of the MTA (Multimodal Treatment of Attention Deficit Hyperactivity Disorder). At the time, the MTA was reviewing the research and experiences of its members in order to recommend an optimal treatment regimen of MPH.

Related to this was the issue of whether twice-a-day ("BID") or three-times-a-day ("TID") dosing would provide the optimal treatment regimen for ADD and ADHD. BID dosing had been the standard for decades, with TID dosing only used in atypical cases. Based on his work from his earlier University of California, Irvine ("UCI") study using TID dosing, Dr. Swanson recommended a TID dosing regimen. This was ultimately accepted by the MTA.

The committee next considered the manner in which the third dose would be administered. The standard practice at that time was to reduce the amount of the third dose (referred to as "sculpting"). But, Dr. Swanson's research recommended that the third dose be equal to the first and second administrations, *i.e.*, a "non-sculpted" or "equal dose" TID regimen. This achieved a drug concentration in the blood that generally rose across the day. Dr. Swanson's research had concluded that this plasma drug profile was critical to maintain efficacy across the day. He referred to this as the "gold-standard" of treatment. Instead of adopting Dr. Swanson's proposed regimen, the other committee members voted to use a sculpted TID regimen, despite Dr. Swanson's demonstration that

non-sculpted TID resulted in increased efficacy later in the day. In September 1993, Dr. Swanson challenged this vote, but he was voted down by the other committee members. (*see, e.g.,* Decl. of L. Eugene Arnold ISO Dr. Swanson's Opp. to ALZA's Mot, for Summary Judgment and Exhibit A thereto; Declaration of Dr. Timothy Wigal ISO Dr. Swanson's Opposition to Motion for Summary Judgment ("T. Wigal Decl.") ¶¶ 3, 7). Named inventor, Dr. Suneel Gupta, corroborated that Dr. Swanson's view of non-sculpted administration differed from the recommendation of the MTA. (Ex. B, Excerpts from 9.12.2014 Depo. of Dr. Gupta, 37:5-13).

Dr. Swanson's recommendation to the MTA to use a non-sculpted TID regimen was based on his knowledge that the pharmacokinetic ("PK") profile needed to obtain the desired pharmacodynamic ("PD") result was one that generally rose across the day, meaning, in the case of a treatment using three pills, each successive peak and valley (there would be three "peaks" using a TID dosing pattern) would be higher than the previous one. (Ex. A, Swanson Inventorship Decl. at 8; T. Wigal Decl. ¶ 6). Stymied by the MTA, Dr. Swanson brought these ideas with him to the first meeting at ALZA on December 6, 1993. Namely, that the generally rising drug concentration associated with his regimen of TID unsculpted treatment was the target profile to shoot for,[2] and the need for a once-daily pill to alleviate embarrassment associated with the mid-day dose then used with TID treatment regimens.

C. Consultant Meeting at ALZA, December 6, 1993

ALZA developed an interest in ADHD in or around 1993 and invited Dr. Swanson to speak about his research and his treatment methods at their offices in Palo Alto, California. (Ex. A at 10-11). Dr. Swanson attended a day-long meeting there on December 6, 1993. Despite ALZA's refusal to admit it in this case, none of ALZA's "inventors" of the Patents-In-Suit had any appreciable experience with ADHD or its treatment prior to meeting with Dr. Swanson. (*see, e.g., Id.* at 9-10, 12; T. Wigal Decl. ¶ 9; Ex. C, ALZA's Suppl. Resp. to Dr. Swanson's First Set of RFAs, at 10). Thus,

[2] Dr. Gupta's testimony corroborates that Dr. Swanson presented the MTA's recommendation of a sculpted dosing regimen, e.g. 10mg/10mg/5mg, and also his non-sculpted dosing regimen, e.g. 10mg/10mg/10mg. This shows that the ALZA scientists understood the important difference between what Dr. Swanson did with his own subjects versus what the rest of the experts in the field were doing. (Ex. B, 37:5-10).

ALZA needed to consult with Dr. Swanson in order to understand the most effective way to treat children with ADHD, as well as the challenges facing school children in obtaining that treatment.

Since he was the only ADHD expert on-hand at the December 6, 1993 meeting, Dr. Swanson spoke for several hours to those attending. (Ex. A, Swanson Inventorship Decl. at 9-10). At this meeting, Dr. Swanson spoke at length about his work with MPH treatment of ADD and ADHD, and recommended his non-sculpted TID regimen, and the resulting generally ascending drug concentration as the target profile. This is corroborated in follow-up e-mails, such as one sent by Dr. Carol Christopher where she responded to a question by stating, '[redacted]" (Ex. D, 12.28.1993 Christopher E-mail).

Additionally, during the December 6, 1993 consultant meeting, Dr. Swanson advocated for the use of a once-daily pill form for the preferred treatment method, and for the use of methylphenidate. At the December 6 consultant meeting, ALZA [redacted] and had not chosen which option to work on. ALZA had also not even chosen whether to use methylphenidate or some other stimulant drug. This is corroborated by Dr. Christopher's e-mail from November 23, 1993 where she first tells the recipients [redacted]. Dr. Christopher concluded the e-mail by stating that '[redacted]" (Ex. E, 11.23.1993 Christopher E-mail) (emphasis in original).

At the December 6, 1993 consultant meeting, Dr. Swanson also advocated the need for using a **once daily pill** (OROS) to deliver the **methylphenidate**. (Ex. A, Swanson Inventorship Decl. at 12 & n. 14). Dr. Swanson's reasoning for advocating for a pill rather than a patch was that, from his own experience in treating children with ADD and ADHD, children suffered from embarrassment from the stigma of wearing a patch to school. As such, Dr. Swanson "recommended a once daily pill delivery system in order for children to avoid the potential embarrassment of having to wear a patch

at school." *Id.* Additionally, Dr. Swanson also spoke during the December 6 meeting about other stimulant drugs other than MPH, namely pemoline and amphetamine, but ultimately recommended the use of methylphenidate, thus answering ALZA's other question of what drug to use. *Id.* at 10.

Upon leaving the consultant meeting, not only did Dr. Swanson feel that the ALZA scientists were generally impressed by his work, but "he was very interested in contributing to the development at ALZA *of [his]* conception of treating ADHD in a manner that achieved a substantially ascending methylphenidate plasma drug concentration across the day with *a single daily administration* instead of by a regime of multiple immediate release doses of methylphenidate given in multiple administrations to the patient each day." *Id.* at 14 (emphasis added). This would not only have the desired benefit of producing the best performance outcomes (PD) for the children, but it would also greatly help the children avoid the embarrassment they traditionally felt during the school day when they would inevitably have to visit the office for their second pill.

D. ALZA Scientists had no Experience with Methylphenidate Prior to Dr. Swanson

None of the named inventors on the Patents-In-Suit had any experience treating, with methylphenidate, patients suffering from ADD or ADHD. Dr. Suneel Gupta, in his most recent deposition, [redacted] (Ex. B, Excerpts from 9.12.2014 Depo. of Dr. Gupta, 28:7-9; 29:7-13). Dr. Carol Christopher, likewise, asserted [redacted]. (Ex. F, Excerpts from 10.25.2013 Depo. of Dr. Christopher, 64:24-66:8). Dr. Sharon Wigal, one of Dr. Swanson's colleagues who also worked with ALZA during the sipping studies, even thought that one of her main jobs was to educate ALZA about ADD/ADHD and methylphenidate. (Ex. G, Decl. of Dr. S. Wigal ISO Dr. Swanson's Inventorship Contentions, ¶ 3).

When asked via a Request for Admission whether any of the inventors named on the Patents-In-Suit had any significant experience in the field of treating patients with ADD or ADHD with methylphenidate, ALZA wordsmithed its response by stating that such information was beyond its control and denied the request based upon lack of knowledge (despite its duty to perform a reasonable investigation) (Ex. C, ALZA's Suppl. Resp. to Dr. Swanson's First Set of RFAs at 10).

ALZA has not and cannot show that any of its "inventors" had any experience with the subject matter of the Patents-In-Suit, namely, treating patients suffering from ADD or ADHD through the use of methylphenidate. As such, ALZA looked to Dr. Swanson to find answers to its questions, and ultimately patented Dr. Swanson's ideas.

E. ALZA looked to Dr. Swanson for a Target Blood Profile

Less than a month following the December 6, 1993 consulting meeting where Dr. Swanson conveyed to ALZA the need to produce a once-daily MPH treatment that resulted in an ascending concentration of the drug in the patient, internal e-mails from various ALZA employees, including one of the named inventors, [redacted]. On December 28, 1993, Larry Hamel, ALZA's head of product development, wrote to Dr. Christopher [redacted]" (Ex. H, 12.28.1993 Larry Hamel E-mail). This is one of the key elements of the claims of the '129 and '798 Patents.

Dr. Christopher responded to Larry Hamel's e-mail later that same day. Dr. Christopher stated that "[redacted] (Ex. D, 12.28.1993 Christopher E-mail). This further substantiates Dr. Tim Wigal's testimony that ALZA, at that time, was known for drug delivery devices, and not for treatment, and would have had no way of conceiving of the idea to use an ascending profile. (T. Wigal Decl., ¶ 9).

Thus, by ALZA's own admission, information presented by Dr. Swanson during the December 6, 1993 consultant meeting provides the basis for the invention claimed in the '129 Patent. ALZA, without Dr. Swanson's talk during the December 6, 1993 consultant meeting, would never have known that an ascending profile was necessary in order to overcome tolerance to MPH treatment. Furthermore, Dr. Swanson's corroborated testimony that he went to ALZA and presented his work on unsculpted TID administration, that it resulted in an ascending profile, and that it was his "gold-standard" in order to maintain efficacy across the day (*e.g.*, overcoming tolerance), shows Dr. Swanson's conception of one of the key elements of the invention claimed in the '129 Patent.

F. Follow-up initiated by ALZA After December 6, 1993

On January 5, 1994, Dr. Christopher called Dr. Swanson at UCI to talk to him regarding [redacted] This is indicated in a January 6, 1993 e-mail that Dr. Christopher sent internally to, among others, Diane Guinta and Suneel Gupta. (Ex. I, 1.06.1994 Christopher E-mail). This e-mail demonstrates that, at least as of January 5, 1994, ALZA had not conceived of how long the delivery of MPH should last. Dr. Swanson's input was required to obtain answers. This additionally corroborates Dr. Swanson's conception.

In Dr. Christopher's January 6, 1994 e-mail, [redacted] More particularly, Dr. Christopher's e-mail indicated that [redacted] According to the e-mail, [redacted] (Ex. I).

In a follow-up e-mail that Dr. Christopher sent later that same day, she stated that she talked to '[redacted] In this e-mail, which included Diane Guinta and Suneel Gupta as recipients, Dr. Christopher indicated that Dr. Shoulson '[redacted] Additionally, Dr. Christopher's e-mail noted that Dr. Kinsbourne agreed with Dr. Shoulson in that he felt that ALZA should have a '[redacted]' Finally, Dr. Kinsbourne [redacted]' (Ex. J, 1.06.1994 Christopher E-mail).

Several facts are apparent. *First*, approximately a month after ALZA brought Dr. Swanson in to teach the ALZA team about MPH treatment of ADD and ADHD, ALZA was clarifying with Dr. Swanson [redacted] This raises questions as to whether the named inventors on the Patents-In-Suit conceived of the subject matter claimed

therein, or whether they merely took and claimed as their own what Dr. Swanson provided to them. *Second*, Dr. Christopher's e-mails demonstrate that the clarifications provided by Dr. Swanson to those questions: 1) [redacted] REDACTED [redacted] From the facts above, it is apparent that the ALZA "inventors" merely reduced to practice Dr. Swanson's concepts and claimed them as their own in the Patents-In-Suit. As just one example, it is readily apparent that ALZA used Dr. Swanson's concept of a once-daily pill resulting in his ascending profile [redacted] REDACTED (Ex. A, Swanson Inventorship Decl. at 12 & n. 14; Ex. D, 12.28.1993 Christopher E-mail).

G. Corroboration of Testimony

Dr. Swanson's recitation of what he brought with him to the December 6, 1993 consultant meeting has ample corroboration. Dr. Marcel Kinsbourne lays out not only foundational evidence that serves to solidify Dr. Swanson's intimate knowledge of the subject matter of methylphenidate being used to treat ADD and ADHD, but also corroborates Dr. Swanson's testimony throughout this case that Dr. Swanson brought with him the knowledge that an ascending blood level of methylphenidate was needed to maintain efficacy. Dr. Kinsbourne stated, in his declaration, that "Dr. Swanson showed that to maintain children's learning at an optimal level, one needs to increase the blood level of methylphenidate over time in the course of a day." (Ex. K, Decl. of Marcel Kinsbourne Corroborating Dr. James M. Swanson's Inventorship Contentions, ¶ 7). Furthermore, Dr. Kinsbourne states that "No one knew that for treatment [of ADD/ADHD] to be effective the serum concentration had to be higher after each dosing than before. Dr. Swanson discovered this relationship; the discovery was his entire brain child." *Id.* Finally, Dr. Kinsbourne also states:

> I do not believe for a moment that ALZA independently came up with this idea. The subject matter of the '129 Patent aligns with Dr. Swanson's' prior research with me at Toronto and the many studies we published together. Our work together provided the underpinning and continuity for what Dr. Swanson recommended to ALZA. I do not believe for a moment that ALZA could have predicted this method of treatment without Dr. Swanson telling them how the drug should be delivered with their technology. *Id.* at ¶ 10.

Dr. Swanson's testimony is further corroborated by Drs. Tim Wigal and Sharon Wigal, who worked with Dr. Swanson during the early 1990s at the UCI. Dr. Tim Wigal, in his Declaration ISO Dr. Swanson's Inventorship Contentions, stated that Dr. Swanson believed that the approach generally accepted by the community at large (*e.g.*, sculpting the final dose) was fundamentally flawed. Most of the sites in the MTA thought that keeping the serum concentration constant and above a threshold would provide effective treatment. Dr. Swanson knew differently. Dr. Swanson "did suggest that a slightly ascending pattern of drug plasma concentration (rather than flat) would combat some of the acute tolerance and maintain efficacy." (Ex. L, Decl. of T. Wigal Corroborating Dr. Swanson's Inventorship Contentions, ¶ 7).

Moreover, Dr. Tim Wigal was also "shocked to see that [the '129 Patent] was not a patent on the ALZA drug delivery technology which ALZA was known for at the time and had impressed me as innovative. Instead, the claim was on Dr. Swanson's idea to administer methylphenidate in a manner that achieves an ascending methylphenidate drug concentration over a time period of about 8 hours following administration. This treatment approach was part of Dr. Swanson's work before I was helping him with the MTA proposal." *Id.* at ¶ 8.

Dr. Sharon Wigal, likewise stated that "[b]ased upon my experience with ALZA during numerous meetings and conference calls, they reviewed what Dr. Swanson came up with in terms of dosing that would lead to a substantially ascending methylphenidate drug concentration over an extended period of time, but they were not the originators of the idea of how to accomplish this. I believe that they could not have developed Concerta without Dr. Swanson's input and ideas in a host of areas including dosing and serum concentrations." (Ex. G, Decl. of Dr. S. Wigal ISO Dr. Swanson's Inventorship Contentions, ¶ 8).

II. ARGUMENT

A. Standards for Summary Judgment

Summary judgment may be granted only when there is no genuine issue of material fact and the movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56. The movant must affirmatively show an absence of evidence to support the nonmoving party's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). The court may not make credibility determinations, and

inferences to be drawn from the facts must be viewed in the light most favorable to the party opposing the motion. *Masson v. New Yorker Magazine, Inc.,* 501 U.S. 496, 520 (1991).

B. Inventorship

Any question regarding the inventorship of the Patents-In-Suit is a question of law. *Shum v. Intel Corp.*, 633 F.3d 1067, 1083 (Fed. Cir. 2010). A person seeking to add his name to the list of inventors on a patent must prove his case by clear and convincing evidence. *Id.* The inventorship analysis must first begin with a proper construction of the claims at issue in order to "determine the subject matter encompassed thereby." *Trovan, Ltd. v. Sokymat Sa*, 299 F.3d 1292, 1302 (Fed. Cir. 2002). After the proper construction of the claims at issue, inventorship is determined on a "claim-by-claim basis," comparing the alleged contributions of each asserted inventor with the subject matter of the properly construed claim. *Id.* (citing *Ethicon, Inc. v. U.S. Surgical Corp.,* 135 F.3d 1456, 1460 (Fed. Cir. 1998)).

In cases surrounding inventorship disputes, "[a] party seeking correction of inventorship must provide clear and convincing evidence of inventorship. To meet this burden, the alleged co-inventors must prove their contribution to the conception with more than their own testimony concerning the relevant facts. Whether the co-inventor's testimony has been sufficiently corroborated is evaluated under a 'rule of reason analysis,' which requires that an '**evaluation of *all* pertinent evidence** must be made so that a sound determination of the credibility of the inventor's story may be reached.'" *Linear Tech. Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1327 (Fed. Cir. 2004) (emphasis added) (citation omitted). Reliable evidence of corroboration specifically includes records made contemporaneously with the inventive process. *Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1350-51 (Fed. Cir. 2001) ("Documentary or physical evidence that is made contemporaneously with the inventive process provides the most reliable proof that the inventor's testimony has been corroborated."). Circumstantial evidence about the inventive process may also corroborate the alleged inventor's testimony. *Knorr v. Pearson*, 671 F.2d 1368, 1373 (CCPA 1982) ("[S]ufficient circumstantial evidence of an independent nature can satisfy the corroboration rule."). Additionally, oral testimony of someone other than the alleged inventor may corroborate. *Gemstar-TV Guide Int'l, Inc. v. ITC,* 383 F.3d 1352, 1382 (Fed. Cir.2004) (*citing Trovan*, 299 F.3d at 1303).

C. ALZA Misapplies the Law

ALZA repeatedly and mistakenly assumes that because "Plaintiff's alleged contributions set forth in his Inventorship Contentions" do not exactly read onto the subject matter of the claims as construed by the court, this entitles ALZA to summary judgment on all counts. This is not the test, and ALZA incorrectly substitutes evidence of inventive conception with Inventorship Contentions. The two are not the same. Dr. Swanson's Inventorship Contentions, which were served in April, 2013, were not intended to be a comprehensive list of all pertinent evidence. Indeed, a substantial portion of the corroborating evidence, much of which was in ALZA's possession, was not even available to Dr. Swanson until later.

ALZA admitted in the Joint Case Management Statement (Dkt. 59) that "this patent case does not involve the usual allegations of patent infringement." *Id.* at 9. Rather, as ALZA pointed out, this case involves Dr. Swanson's claims that he should be listed as an inventor on the Patents-In-Suit. ALZA complained that Dr. Swanson's Amended Complaint, despite largely surviving ALZA's Motion to Dismiss, "provided scant detail as to what precisely Plaintiff believes he invented." *Id.* ALZA further complained that "[w]hile the Amended Complaint identifies a few claims in the ALZA patents that Plaintiff believes he contributed to, it is not clear that the list is exhaustive." *Id.* at 10. Because of this perceived ambiguity, ALZA requested that the Court order Dr. Swanson to prepare and serve Inventorship Contentions so that "ALZA will be in a position **to identify claim terms** it believes ought to be construed." *Id.* (emphasis added). ALZA never advocated that all evidence be listed in Dr. Swanson's Inventorship Contentions.

ALZA now asks the Court to take Dr. Swanson's Inventorship Contentions, which were prepared and served without any discovery from ALZA, as the sole basis for granting it Summary Judgment. This stance belies ALZA's true intention that it would like this Court to grant it Summary Judgment without reaching the actual merits of the case. Based upon these preliminary contentions, and without providing any legal precedent, ALZA now asks the Court to rule against Dr. Swanson.[3]

[3] There is no Patent Local Rule that requires Dr. Swanson to serve Inventorship Contentions that are "similar to infringement contentions," thus the rationale behind the Patent Local Rule does not apply. Although ALZA would like to single out Dr. Swanson's Inventorship Contentions, this has no merit because it is the evidence which *supports* those Contentions that must be examined by the Court.

ALZA bases its entire Motion for Summary Judgment on a comparison between Dr. Swanson's Inventorship Contentions and the claims as construed by the Court. However, this strategy is not supported by caselaw. ALZA, in its Motion, improperly attempts to limit the scope of evidence to be considered to evidence served along with the Inventorship Contentions. Dr. Swanson anticipates that ALZA will attempt to exclude any evidence presented by Dr. Swanson that was not provided at that time, even evidence to which he did not have access to when the contentions were served. However, this attempt to narrow the scope of its Motion is contrary to established caselaw that holds that "***all pertinent evidence***" must be evaluated when determining whether an alleged inventor's testimony is corroborated. *Linear Tech.*, 379 F.3d at 1327.

ALZA's use of facts and arguments falling outside of Dr. Swanson's Inventorship Contentions and the Court's Claim Construction Order demonstrates that ALZA acknowledges that evidence outside of this narrow scope must be considered. By way of example, ALZA, in its brief, cites to its own Claim Construction Brief and Reply Brief (Dkt. 170 at 2), Dr. Swanson's Declaration In Support of His Claim Construction Brief (Dkt. 170 at 4); and even the transcript from the *Markman* hearing (Dkt. 170 at 9-10). By bringing in evidence outside of Dr. Swanson's Inventorship Contentions and comparing that evidence to the Court's Claim Construction Order, ALZA has implicitly acknowledged that this Motion should consider the full and complete record, not just the record to which ALZA attempts to limit Dr. Swanson.

D. ALZA's "Undisputed Facts"

ALZA rests its argument on the flawed assumption that for Dr. Swanson to be listed as an inventor on the '129 and '798 Patents, these patents would have to cover TID administration of MPH. This is argument only, and this argument disingenuously overlooks specific factual evidence set forth in the Declarations of Drs. Swanson, T. Wigal, S. Wigal, and Kinsbourne served with Dr. Swanson's Inventorship Contentions. For example, ALZA contends that "Plaintiff pursued claim constructions that encompassed this TID unsculpted regimen – constructions that ***were necessary*** for Plaintiff to argue that his work with TID dosing supports his claim of inventorship." (Dkt. 170 at 9) (emphasis added). This is simply not the case.

The purpose of a *Markman* hearing is to "ascertain the meaning of [the] claims." *Markman v. Westview Instruments*, 52 F.3d 967, 979 (Fed. Cir. 1995). In determining the meaning of the claims, a court will consider the claims, the specification, and the prosecution history. *Id.* Expert testimony as well as extrinsic evidence may be considered by the court. *Id.* at 980-81. However, ALZA now contends that Dr. Swanson's proposed constructions of the terms in dispute were put forward by Dr. Swanson in order for the claims to cover Dr. Swanson's previous work. Instead, the proposed constructions of the terms in dispute were advocated because that is what Dr. Swanson considered to be the proper scope of the claims, especially when read in light of the history of the patents (*e.g.*, that ALZA admitted it did not have a working once-daily administration at the time it filed its first provisional application). Dr. Swanson had meritorious arguments that related directly back to the prosecution history of the patents in dispute and even referenced arguments that at least one other court found to be a close call, namely, whether the '129 Patent covered single or multiple daily administration of MPH.

ALZA additionally argues that Dr. Swanson's evidence relating to inventorship of the claims at issue must be limited to any invention that he developed prior to the December 6, 1993 consultant meeting that took place at ALZA. (Dkt. 170 at 7). Moreover, ALZA argues that "Plaintiff cannot rely on the sipping studies as the basis for any of his inventorship claims." *Id.* In so arguing, however, ALZA overlooks that Dr. Swanson was the principal investigator and designer of the sipping studies – he was an integral member of the team, and he was in the best position to design a study and evaluate its results that reduced his invention to practice. (Ex. A, Swanson Inventorship Decl. at 14-20). However, ALZA has provided no authority to support this, and instead relies upon Dr. Swanson's Inventorship Contentions and discovery responses that relate back to those same Inventorship Contentions. As already discussed above, this reliance upon Dr. Swanson's Inventorship Contentions is misplaced as they were prepared and served only as a means to limit the number of claim terms to be construed. Additionally, these Inventorship Contentions were prepared

without a complete record of discovery,[4] a record that has still not been completed as ALZA continues to stonewall additional, relevant discovery.[5]

ALZA's attempt to limit Dr. Swanson's presentation of facts to anything prior to the December 6, 1993 consultant meeting contravenes caselaw which unambiguously holds that "***all pertinent evidence***" must be evaluated when determining whether an alleged inventor's testimony is corroborated. *Linear Tech.*, 379 F.3d at 1327. Although Dr. Swanson's Inventorship Contentions do submit that he had developed and used TID unsculpted MPH administration prior to coming to ALZA, this in no way dictates that the Court must ignore evidence which supports those contentions.

E. Triable Issues Material Fact

ALZA's Motion can be summarized in one sentence: ALZA contends that, following "the Court's claim construction, there is no longer any dispute that the claims at issue do not encompass the TID regimen and associated plasma drug concentration profile that Plaintiff alleges to have invented." (Dkt. 170 at 10) (emphasis removed). This, however, mistakenly equates Dr. Swanson's unsculpted TID administration of MPH to treat ADD and ADHD as the outer limit of Dr. Swanson's inventive idea, and fails to take into account ALZA's own documents that give Dr. Swanson credit for, as ALZA puts it in the patents, its "surprising discovery." Moreover, Dr. Swanson's inventorship claims are supported not only by his own testimony, but also by his publications, corroboration testimony of others that worked with Dr. Swanson at the time, another one of ALZA's own consultants, and even ALZA's own employees (including some of the named inventors) and documents. Because of the overwhelming amount of evidence that speaks directly to Dr. Swanson's key role in the development of the Patents-In-Suit, many triable issues of material fact remain. When read in a light most favorable to Dr. Swanson, the evidence clearly and convincingly establishes his

[4] ALZA's first production of documents and things to Dr. Swanson occurred on June 11, 2013, almost two months after the Inventorship Contentions were served. (Ex. M, June 11, 2014 Letter to Dodson). ALZA later admitted that this first production did not even include ESI documents that were run with the basic term "Swanson." (Ex. N, August 27, 2013 Letter to Boyle). After disclosing that it did not run this term, it took ALZA more than a month to agree to use the term "Swanson" in addition to other simple terms for this case. (Ex. O, September 30, 2014 Letter to Dodson).

[5] ALZA refuses to present for deposition various named inventors, as well as ALZA's prior Litigation Counsel.

inventorship. As such, ALZA's Motion for Summary Judgment should be denied.

i. Dr. Swanson is the sole inventor of Claims 1 and 2 of the '129 Patent

Despite ALZA's contentions to the contrary, there are issues of material fact remaining surrounding the issue of whether Dr. Swanson is the sole inventor of claims 1 and 2 of the '129 Patent.

"administering a pharmaceutically acceptable composition comprising methylphenidate and a pharmaceutically acceptable carrier to said patient"

Both claims 1 and 2 of the '129 Patent recite, in part, "administering a pharmaceutically acceptable composition comprising methylphenidate and a pharmaceutically acceptable carrier to said patient." The Court construed this to mean "administering a pharmaceutically acceptable composition comprising methylphenidate once-daily." (Dkt. 157 at 29). ALZA makes much of the fact that Dr. Swanson claims to have only brought with him TID (three daily doses) administration of methylphenidate, but fails to account for several major facts that undermine ALZA's assertion that Dr. Swanson did not conceive of the inventions in the '129 patent.

First, as already established above, as of approximately two weeks prior to the December 6, 1993 consultant meeting, [redacted]. This is memorialized in a November 23, 1993 e-mail sent from Dr. Carol Christopher to a number of individuals at ALZA where she stated [redacted]" (Ex. E, 11.23.1993 Christopher E-mail). Dr. Swanson, as is established in his declaration, provides testimony that he recommended the "need for a once a day pill." (Ex. A, Swanson Inventorship Decl. at 12). Dr. Swanson was aware that ALZA was still up in the air between an OROS pill and a transdermal patch (TTS), and based his recommendation on his knowledge about the stigma associated with wearing a skin patch at school. "As evidenced by the December 6, 1993 agenda, ALZA still had not decided upon the methylphenidate delivery system to employ (i.e. TTS® skin patch or OROS® pill). I recommended a once a day pill in order for children to avoid the potential embarrassment of having to wear a patch at school." *Id.* at n. 14. This is

corroborated [redacted]. (Ex. R, Meeting Agenda for December 6, 1993 Consultant Meeting at ALZA at 1). ALZA's lack of a clear and concise idea coming into the December 6 consultant meeting, coupled with Dr. Swanson's own testimony and reasoning behind his testimony regarding his recommendation for once daily methylphenidate, creates a material issue of fact. What is more, this material issue of fact is established within Dr. Swanson's inventorship contentions.

ALZA relies heavily on its reading of Dr. Swanson's Inventorship Contentions and discovery responses. For example, ALZA attempts to make "something out of nothing" when it states that "Plaintiff alleges only conception of methods and compositions involving IR-MPH given TID in equal doses." (Dkt. 170 at 11) (emphasis in original). However, even putting aside the testimony of Dr. Suneel Gupta (one of ALZA's primary scientists named on the '129 Patent) [redacted] (Ex. B, Excerpts from 9.12.2014 Depo. of Dr. Gupta, 37:5-10), ALZA's statements are factually incorrect. For example, in support of its Motion, ALZA falsely states that "[n]owhere does Plaintiff allege conception of a once-daily MPH treatment as claimed in the '129 Patent." (Dkt. 170 at 11). However, as already shown above, Dr. Swanson alleged conception of once-daily MPH treatment on page 12 of his Inventorship Decl. ALZA conveniently forgets to mention this statement in its Motion. Importantly, as ALZA has presented no contradictory evidence that Dr. Swanson did not allege conception of once daily administration of MPH to treat ADD and ADHD, ALZA has not demonstrated any evidence that contradicts Dr. Swanson's declaration that falls in line with contemporaneously created records. Thus, triable issues of material fact remain as to who conceived of the idea of utilizing a once-daily administration of methylphenidate as claimed in the '129 Patent.

"in a manner that achieves a substantially ascending methylphenidate plasma drug concentration"

Both claims 1 and 2 of the '129 Patent recite, in part, "in a manner that achieves a substantially ascending methylphenidate plasma drug concentration over a period of about [x] hours following said administration." As construed by this Court, this claim term means "a profile in which

the plasma concentration of methylphenidate generally rises over approximately [x] hours," with [x] hours being either 8 hours or 9.5 hours, depending on claims 1 or 2, respectively. (Dkt. 157 at 29). Dr. Swanson conceived of the idea of a generally ascending plasma drug profile over the course of 8 or 9.5 hours. There are at least two ways that Dr. Swanson conveyed the idea of a generally ascending plasma drug profile to people at ALZA during the December 6, 1993 consultant meeting.

Dr. Swanson's Unique Knowledge and Pharmacokinetic Principles Resulted in Claims 1 and 2 of the '129 Patent

Dr. Swanson is a pioneer in the study of MPH pharmacokinetics and pharmacodynamics[6] in the treatment of ADD and ADHD. (Declaration of C. Lindsay DeVane in Support of Plaintiff Dr. James M. Swanson's Opposition to ALZA's Motion for Summary Judgment ("DeVane Decl.") ¶ 16). Dr. Swanson's unique knowledge and pharmacokinetic principles were responsible for claiming a generally rising plasma drug concentration of MPH for the treatment of ADD and ADHD in the '129 Patent. (DeVane Decl. ¶ 17).

Characteristics of MPH uniquely known by Dr. Swanson and pharmacokinetic principles known in 1993 make this true. First, the elimination half-life of MPH in patients (time at which 50% of a drug disappears from the circulation) was known in 1993 to be 2 to 3 hours. (DeVane Decl. ¶ 19). Second, Dr. Swanson's work demonstrated that MPH exhibits linear or "first order kinetics"[7] well before 1993. (DeVane Decl. ¶ 20). The rate of MPH absorption and elimination from the MPH plasma drug concentration is proportional to the amount of MPH in the body. (DeVane Decl. ¶ 22). For MPH, this means that its half-life remains constant, *i.e.*, it does not change as the plasma drug concentration changes. (DeVane Decl. ¶ 23). Third, uniquely known by Dr. Swanson in 1993, his

[6] "Pharmacokinetics" describes the effect of the body on a drug (e.g. absorption, distribution, metabolism, excretion). Plasma drug concentrations as described in the '129 Patent are a common metric used in the field of Pharmacokinetics. "Pharmacodynamics" describes the effect of the drug on the body or patient. (DeVane Decl. ¶ 18).

[7] Once a drug reaches the circulation, its absorption into, and elimination from the body is described as "linear" or "first order" when these rates are proportional to the amount of drug in the body. (DeVane Decl. ¶ 21).

TID non-sculpted regimen produced the desired clinical effects, overcoming effects that may be associated with acute tolerance.[8] (T. Wigal Decl., ¶ 5-6).

Combining Dr. Swanson's unique knowledge with pharmacokinetic principles known in 1993 produced claims 1 and 2 of the '129 patent. It follows that administering 10 mg of MPH non-sculpted at 0, 4, and 8 hours produces increasingly ascending peaks, troughs, and average drug concentrations over the period of administration. (DeVane Decl. ¶ 24). Upon the second administration of 10 mg of MPH at 4 hours, the remaining MPH administered at 0 hours is not fully eliminated from the body because of MPH's 2-3 hour half-life. *Id.* Accordingly, the second administration of 10 mg of MPH is added to the remaining MPH administered at 0 hours to produce a resulting plasma drug concentration greater than what was produced by the first administration at 0 hours. *Id.* Likewise, the amount of the remaining MPH at 8 hours is higher than the amount of the remaining MPH at 4 hours, because linear kinetics dictates that the half-life of MPH will not change even if MPH concentrations rise in the plasma, and the peak concentration produced by the second administration is higher than the peak concentration produced by the first administration. *Id.* The same holds true for the third administration at 8 hours: the third peak concentration is higher than the second peak concentration and the third trough concentration is higher than the second trough concentration, which continues to produce a generally rising MPH plasma drug concentration throughout the day. *Id.* This would not be the case if the third administration at 8 hours was sculpted, *i.e.*, the MPH plasma drug concentration would not continue to generally rise. *Id.* Thus, assuming Dr. Swanson advised ALZA to forgo the sculpting of the last dose, (Ex. A, Swanson Inventorship Decl. at 12, 16) it was pivotal for establishing a generally rising MPH plasma drug concentration throughout the day for the optimal treatment of ADD and ADHD. *Id.*

Profile Resulting From Non-Sculpted TID Administration Generally Rises

ALZA, throughout its Motion, repeatedly claims that pursuant to the Court's claim construction order, the plasma profile resulting from TID administration, even unsculpted, cannot be read into the claims. For example, on page 1 of its Motion, ALZA states that "The Court concluded that ALZA's '129 and '798 patents cover only once-daily MPH administration that is "clearly

[8] The *Andrx* Court said that as of the time of the filing of the parent '373 Patent, acute tolerance was merely "a hypothesis." (Ex. S, March 30, 2009 Opinion from *Alza v. Andrx*, Dist. Delaware, Civil Action No. 05-642-JJF).

distinguished in the patent over prior art TID regimes" and that necessarily excludes the peaks-and-troughs plasma drug concentration profiled produced by TID administration." (Dkt. 170 at 1). This is not an accurate representation of the Court's construction. The Court held: "TID dosing involves three IR administrations spaced hours apart, and results in 'peaks and troughs' in plasma drug concentrations. By contrast, ALZA's invention concerns a once-daily dosage form resulting in 'substantially ascending plasma drug concentration' over time, which is clearly distinguished in the patent from prior art TID regimes." (Dkt. 157 at 17). However, the court did not find, as ALZA now argues it did, that an ascending peak-and-trough, or ascending sawtooth, is a plasma drug profile that does not "generally rise." Moreover, as was made clear at the September 3, 2014 hearing on Dr. Swanson's Motion for Leave to Amend his Inventorship and Invalidity Contentions, the Court found that the limitation proposed by ALZA "may include a slight dip" "simply reinforces the concept that the plasma drug concentration 'substantially' or 'generally' or 'approximately' rises, but may also briefly descend." (Dkt. 157 at 15).

Throughout this litigation, Dr. Swanson has contended that an ascending sawtooth plasma drug profile is one that "generally" or "substantially" or "approximately" rises, but may also briefly descend. Dr. Swanson's contention is further supported by testimony by one of the named inventors, Dr. Suneel Gupta. Dr. Gupta testified [redacted] (Ex. B, Excerpts from 9.12.2014 Depo. of Dr. Gupta, 37:5-10). Moreover, Dr. Gupta testified in 2006 in the *Andrx* case, as ALZA's 30(b)(6) designee, that [redacted]. (Ex. P, Excerpts from 10.04.2006 Depo. of Dr. Gupta, 117:14-118:13, 120:5-16*, 126:22-127:10*, 128:7-10*[9]).

[9] It should be noted that those excerpts from the 2006 Gupta deposition transcript that include an asterisk had their answers substantively changed in the errata and marked as "clarification." These suspect "clarifications" in the errata read: '[redacted]

Using ALZA's own definition, as supplied by its 30(b)(6) designee in 2006, an ascending sawtooth drug plasma profile, similar to one which would be produced by a TID unsculpted regimen, and which contains drops of less than 50% drug concentration and then goes back up again in a short time window, is considered by ALZA to be a "substantially ascending profile." ALZA admits the fact that during the December 6, 1993 consultant meeting at ALZA, Dr. Swanson told a number of ALZA employees, including several of the named inventors, about his work with unsculpted TID administration of methylphenidate and how the unsculpted nature was necessary to produce the best PD results because it overcame tolerance. Dr. Swanson further testified that he told ALZA that it was the rising aspect of the TID peak and valley profile that produced the desired, steady PD results in his patients. (Ex. A, Swanson Inventorship Decl. at 12-14). It was this rising nature of the peak and valley profile that produced results better than those of Ritalin SR®, the only once-daily MPH product on the market at that time. *Id.* at 15 ("I presented data from my previous research that showed the plasma concentrations that [TID unsculpted] dosing would produce. These plasma concentrations achieved successively higher peaks and thus a 'substantially ascending' methylphenidate plasma drug concentration throughout the school day. I recommended this as the 'gold standard' because with an ascending methylphenidate drug concentration throughout the day, the full efficacy of treatment on the child's behavior would remain present across the day."). The reason, Dr. Swanson told ALZA, that TID unsculpted worked better that Ritalin SR or even TID sculpted, was that the rising profile was needed to overcome the acute tolerance to MPH built up during the day by the body. Dr. Swanson's testimony is corroborated by the sworn declarations of his contemporaries, and even ALZA's internal e-mails.

In an e-mail that Diane Guinta sent in response to Dr. Christopher's January 6, 1994 e-mail, Dr. Guinta noted [redacted] (Ex. Q, 1.06.1994 Christopher E-mail) (emphasis added). With the context supplied above, there remains a distinct material issue of fact regarding [redacted]

Additionally, as reflected in the concurrently filed declaration of Tim Wigal In Support of Dr. Swanson's Opposition to ALZA's Motion for Summary Judgment, Dr. Swanson was aware of and appreciated the relationship between the ascending serum concentration produced by his non-sculpted TID treatment regimen and acute tolerance to methylphenidate in a patient. Dr. Wigal stated that "our patients were obtaining the desired clinical effect with a t.i.d. non-sculpted regimen." (T. Wigal Decl., ¶ 5). Dr. Wigal further stated that based upon these observations, Dr. Swanson knew that acute tolerance was developing, and that Dr. Swanson's "idea . . . was to deliver a regimen that produced an ascending plasma profile across the day to overcome effects that might be associated with acute tolerance." *Id.* at ¶ 6. From observing the behavioral outcomes associated with Dr. Swanson's gold standard, "we believed that there must be a corresponding plasma blood profile of methylphenidate that ascended across the day." *Id.* Dr. Swanson knew that his gold standard profile was one that produced a MPH serum concentration that ascended across the day because of his observed results with his own subjects.

Based upon ALZA's complete lack of experience in treating ADD and ADHD patients with methylphenidate, and in conjunction with Dr. Swanson's wealth of experience and knowledge that an ascending profile provided the optimal treatment, there can be no reasonable debate that a material issue of fact still exists with respect to this claim element.

"over a time period of about [8 or 9.5] hours following said administration"

Finally, as was already discussed above, [redacted] Dr. Christopher, in an internal ALZA e-mail, indicated [redacted] Dr. Christopher first reached out to Dr. Swanson on January 5, 1994. In a January 6, 1994 e-mail to members of ALZA, Dr. Christopher wrote [redacted] Dr. Swanson, according to Dr. Christopher's e-mail, [redacted] (Ex. I, 1.06.1994 Christopher E-mail). In

another e-mail later that day, Dr. Christopher said [redacted] (Ex. J, 1.06.1994 Christopher E-mail).

Out of the three consultants ALZA contacted, namely, Dr. Swanson, Dr. Kinsbourne, and Dr. Shoulson, [redacted] This demonstrates that Dr. Swanson had a clear and concise idea about the period of treatment, namely, 8 hours. This same period of treatment appears exactly in Claim 1 of the '129 Patent, yet ALZA claims that its own scientists came up with this time period independently of Dr. Swanson. There can be no reasonable debate that Dr. Swanson was in possession of a clear and concise inventive concept during his initial consultation with ALZA in December, 1993. When asked for follow-up help, [redacted] More importantly still, these answers appear in the issued claims of the '129 Patent.

ALZA, meanwhile, has never claimed, nor does it do so now, that its own inventors came up with the concept of 8 hours of treatment. The closest ALZA has come to doing so was in Dr. Christopher's deposition:

[redacted]

(Ex. F, Excerpts from 10.25.2013 Depo. of Dr. Christopher, 235:2-12).

However, Dr. Christopher could not describe any clear and concise conception of ALZA's with respect to the idea to use 8 hours of coverage. Instead, as her prior e-mails show, [redacted]

[redacted] REDACTED [redacted][10], there can be no reasonable debate that there exist contemporaneously created documents that corroborate Dr. Swanson's testimony that he conveyed this claim limitation to ALZA.

For at least the foregoing reasons, there still exist triable issues of material fact as to whether Dr. Swanson is the sole inventor of claims 1 and 2 of the '129 Patent.

ii. Precedent Supports Dr. Swanson's Inventorship Claims

Ethicon supports the finding of a genuine issue of material fact here to defeat ALZA's summary judgment motion. In *Ethicon*, the Federal Circuit affirmed a Connecticut district court decision adding an intervener's name to a patent for a surgical tool used in endoscopic surgery. *Ethicon*, 135 F.3d at 1458. Dr. Yoon, the man who obtained the patent originally in *Ethicon,* began working on a safer surgical tool that would result in fewer injuries during surgery. *Id.* at 1459. Dr. Yoon consulted with Choi, an electronics technician who intervened in an action to enforce the patent that Dr. Yoon had originally obtained on the surgical tool. *Id.* Dr. Yoon never informed Choi that he had filed for and received a patent. *Id.* The district court found, and the Federal Circuit affirmed, that Choi had made specific contributions to certain claims of the patent. *Id.* at 1462. Namely, Choi conceived of a method for constructing the surgical instrument such that it would work in the manner that Yoon intended. *Id.*

In discussing the district court's finding, the Federal Circuit reiterated that the alleged co-inventor's testimony must show inventorship by clear and convincing evidence, and that testimony by the alleged inventor must be corroborated with other evidence, judged under a rule of reason analysis. *Id.* at 1464. The Federal Circuit held that "the trial court must consider corroborating evidence in context, make necessary credibility determinations, and assign appropriate probative weight to the evidence to determine whether clear and convincing evidence supports a claim" of inventorship. *Id.* Further discussing the trial court's findings, the Federal Circuit cited with approval the district court's findings of several factors that corroborated Choi's conception claim, namely: "(1) Yoon's need for a person with expertise in electronics; (2) Choi's background in electronics, (3)

[10] Dr. Gupta testified that the point of novelty for Claim 1 of the '129 Patent was "[redacted] REDACTED [redacted] (Ex. B, 78:8-19).

Yoon's proposal that he and Choi should work together to develop new products, including safety trocars, (4) their informal business relationship, (5) the length of time they worked together, (6) the absence of any pay to Choi for his work, (7) the similarity between Choi's sketches and the patent figures, and (8) the letter in which Choi stated that he could no longer be a "member" of Yoon's business." *Id.*

Similarly, here Dr. Swanson was never informed by ALZA that it filed a patent application on a method for treating ADHD that included the elements of the claims that Dr. Swanson had presented to ALZA at the December 1993 consultant meeting at ALZA in Palo Alto, California. Notably, the original provisional patent application did contain TID dosing of methylphenidate, and even with this Court's finding that the claims at issue in the Patents-In-Suit do not now include TID dosing, Dr. Swanson clearly presented the other elements of claims 1 and 2 of the '129 patent before ALZA conceived of anything, including once-daily dosing. ALZA was only pondering the use of various technologies developed by them and well known in the art at the time. Dr. Swanson, like Choi, in order to corroborate his claim of inventorship, has presented contemporaneous evidence that he, and *not* the ALZA team led by Dr. Gupta, originally conceived of at least certain elements of the patented method for treating ADHD.

Additionally, here as in *Ethicon*, the Court is being presented with several similar, if not identical factors and evidence that corroborate Dr. Swanson's testimony. Many of these track directly onto the factors cited with approval by the Federal Circuit, such as: (1) ALZA's need for Dr. Swanson's experience with methylphenidate treatment for ADD and ADHD, (2) Dr. Swanson's background with methylphenidate and treating patients with ADD and ADHD, (3) ALZA's proposal that Dr. Swanson work with ALZA on the methylphenidate project; (4) ALZA's business relationship with Dr. Swanson, namely his status as a consultant; (5) the years that ALZA spent working with Dr. Swanson; and (6) the similarity between "ALZA's invention" and Dr. Swanson's work with TID unsculpted dosing. In holding with Federal Circuit case law, these factors confirm that Dr. Swanson's testimony is corroborated.

iii. There is no question that Dr. Swanson is at least a co-inventor of the '129 Patent

Alternatively, under the law, Dr. Swanson is at least a co-inventor on the '129 Patent. Each joint inventor "must contribute to the joint arrival at a definite and permanent idea of the invention as it will be used in practice." *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1229 (Fed. Cir. 1994). But, "each contributor need not have their own contemporaneous picture of the final claimed invention in order to qualify as joint inventors." *Vanderbilt Univ. v. ICOS Corp.*, 601 F.3d 1297, 1303 (Fed. Cir. 2010). For example, by statute, joint inventors need not contribute to every claim of a patent—"[a] contribution to one claim is enough." *Ethicon*, 135 F.3d at 1460; 35 U.S.C. § 116. Indeed, "[o]ne need not alone conceive of the entire invention, for this would obviate the concept of joint inventorship." *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997). As demonstrated in Dr. Swanson's Declaration In Support of his Inventorship Contentions, Dr. Swanson's work with various ALZA employees leading up to and during the first sipping study, establishes the necessary evidence that he was at least a joint inventor of the claims of the '129 Patent, and played an important role in the joint arrival of a definite and permanent idea of the claim element of the invention "to achieve a substantially ascending methylphenidate plasma drug concentration over a time period of about 8 hours following said administration" as required by claim 1 and dependent claims 3-6 of the '129 patent. (Ex. A, Swanson Inventorship Decl. at 17). Dr. Swanson contends that he contributed to both conception and reduction to practice of the claims of the '129 patent. He goes on to discuss his further contributions to entitle him to at least joint inventorship status on the '129 patent.

The Court's claim construction of once a day dosing that ALZA relies on to try to defeat any claim that Swanson may have to sole inventorship on the '129 patent does not take away from the other significant contributions that Swanson made that create a genuine issue of material fact as to whether Swanson is a co-inventor on the claims of the '129 patent.

iv. Dr. Swanson is at least a co-inventor of the '798 Patent

Although ALZA argued that Dr. Swanson does not allege collaboration with ALZA regarding his claim of joint inventorship of the claims of the '798 Patent (Dkt. 170 at 16), this is simply not the case. As just one example, Dr. Swanson states that "[f]ollowing [the] initial meeting at ALZA on

December 6, 1993, I had numerous subsequent conference calls and meetings discussing the work that was going to be jointly done by ALZA and me, in which ALZA confirmed my recommendations for treatment of children with ADHD." (Ex. A, Swanson Inventorship Decl. at 15). Significantly, ALZA does not disclose this testimony in its Motion, and instead only makes a blanket statement that "Plaintiff has failed to allege or provide evidence showing that he made any contributions to the inventions of the disputed claims of the '798 Patent in collaboration with the ALZA inventors." (Dkt. 170 at 16) (emphasis in original).

There is additional evidence that Dr. Swanson supplied valuable concepts to at least Claims 1 and 7 of the '798 Patent:

Claims 1 and 7: An oral tablet dosage form for the treatment of ADD or ADHD in a subjection comprising

Dr. Swanson recommended the need for a once a day pill that was still being considered by the ALZA group. As discussed previously, ALZA still had not decided whether to use an OROS® pill or a TTS® skin patch. (Ex. A at 12). This is corroborated [redacted] (Ex. R, Meeting Agenda for December 6, 1993 Consultant Meeting at ALZA at 1).

Claim 1: an immediate release portion comprising methylphenidate or a pharmaceutically effective salt thereof / Claim 7: an immediate release coating comprising methylphenidate hydrochloride

Dr. Swanson recommended during his collaboration with ALZA that the sipping study should use "an initial bolus followed by an ascending profile, but [ALZA's] Dr. Gupta recommended an ascending profile without a bolus," based on his own previous experience. (Ex. A at 15, 17). The initial bolus concept became the immediate release portion or coating. This concept is corroborated by one of Dr. Swanson's colleagues at UCI, Dr. Tim Wigal: "This clinical effect first occurs after the 'ramp effect' or a relatively rapid increase in plasma drug concentration after an initial dose or bolus . . . merely keeping the concentration constant fails to maintain that . . . effect . . . [Dr. Swanson] did

suggest that a slightly ascending pattern of drug plasma concentration (rather than flat) would combat some of the acute tolerance and maintain efficacy." (T. Wigal Decl., ¶ 7).

Based upon the testimony supplied by Dr. Swanson in his Declaration In Support of His Inventorship Contentions, as well as the corroborating evidence already discussed above, there remain material issues of fact as to whether Dr. Swanson is at least a co-inventor of Claims 1 and 7 of the '798 Patent. More specifically, Dr. Swanson's testimony discussed above recalls specifically that Dr. Swanson was the sole person at ALZA on December 6, 1993 with the firm and concrete idea formed in his mind that the invention must use an oral dosage form instead of a patch or TTS system. Additionally, Dr. Swanson was the sole person to advocate for the use of methylphenidate instead of alternative stimulant medications then being considered by ALZA. Based upon these contributions, as well as his lengthy work with ALZA, Dr. Swanson has demonstrated that there remain triable material issues of fact surrounding his status as a co-inventor on the '798 Patent.

F. Because Triable Material Issues of Fact Remain Regarding Dr. Swanson's Status as an Inventor, the Other Counts in Dr. Swanson's First Amended Complaint are not Ripe for Summary Judgment

In its Motion, ALZA argues that the remaining counts contained within Dr. Swanson's First Amended Complaint are all dependent upon Dr. Swanson's allegation that he is an inventor of the '129 and '798 Patents. As Dr. Swanson has demonstrated above, there remain material triable issues of fact surrounding Dr. Swanson's status as an inventor on these patents. Because of this, and based upon ALZA's own arguments, there remain triable issues of fact surrounding the remaining counts in Dr. Swanson's First Amended Complaint, thus rendering them not ripe for summary judgment.

III. CONCLUSION

For at least the above reasons, Dr. Swanson has demonstrated material issues of fact over which reasonable minds could differ. ALZA's claim that it is entitled to summary judgment based upon a simple and direct comparison between Dr. Swanson's Inventorship Contentions, which were prepared and served without even the benefit of ALZA's own production, and the Court's Claim Construction order has been disproven. ALZA brazenly omitted key portions of testimony provided in Dr. Swanson's Inventorship Contentions that create material issues of fact, and failed to address key evidence (that was in ALZA's possession at the time the Inventorship Contentions were

prepared) that shows that ALZA's "inventors" took Dr. Swanson's conception and patented it without ever once informing Dr. Swanson of their true intentions. Dr. Swanson respectfully requests that the Court deny ALZA's Motion for Summary Judgment.

Dated: October 1, 2014

CARR & FERRELL LLP

By /s/ Robert J. Yorio
ROBERT J. YORIO
K. BRIAN BATHURST
BRYAN J. BOYLE
MICHAEL T. ADELSHEIM

APPENDIX A

Exhibit A – Swanson Declaration ISO Inventorship Contentions – NOT SEALED

Exhibit B – Excerpts from 2014 Gupta Deposition – SEALED

Exhibit C – ALZA Supplemental Responses to RFAs – NOT SEALED

Exhibit D – ALZA00147139 – SEALED

Exhibit E – ALZ00147145 – SEALED

Exhibit F – Excerpts from 2013 Christopher Deposition – SEALED

Exhibit G – S. Wigal Declaration ISO Inventorship Contentions – NOT SEALED

Exhibit H – ALZA00147142 – SEALED

Exhibit I – ALZ00171629 – SEALED

Exhibit J – ALZ00163157 – SEALED

Exhibit K – Kinsbourne Decl. ISO Inventorship Contentions – NOT SEALED

Exhibit L – T. Wigal Declaration ISO Inventorship Contentions – NOT SEALED

Exhibit M – 2013.06.11 ALZA Ltr. Re Production – NOT SEALED

Exhibit N – 2013.08.27 ALZA Ltr. Re ESI Search Terms – NOT SEALED

Exhibit O – 2013.09.30 – ALZA Ltr. Re ESI Search Terms – NOT SEALED

Exhibit P – Excerpts from 2006 Gupta Deposition – SEALED

Exhibit Q – ALZ00171627 – SEALED

Exhibit R – SWAN00044327-335 – SEALED

Exhibit S – March 30, 2009 Op. from ANDRX – NOT SEALED